

510(k) Summary of Safety and Effectiveness
Somnus Medical Technologies, Inc.™
Model 3000 Disposable Tri-Needle Coagulating Electrode
11-28-96

DEC 16 1996

K963884

Intended Use:

The Somnus™ Model 3000 Disposable Tri-Needle Coagulating Electrode is intended for use in the coagulation of tissue. The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Submitted By:

Somnus Medical Technologies, Inc.
995 Benecia Avenue
Sunnyvale, CA 94086
Tel: 408-773-9121
Fax: 408-773-9137

Contact Person:

Eve A. Conner, Ph.D.
Vice President, Clinical and Regulatory Affairs
Tel: 408-524-6263
Facsimile: 408-524-6264

Name of Device:

Proprietary Name:	Somnus Model 3000 Tri-Needle Coagulating Electrode
Common/Usual Name:	Electrosurgical
Classification Name:	Electrosurgical Device (per 21CFR 878.4400)

Description:

The Somnus Model 3000 Disposable Tri-Needle Coagulating Electrode is an electrosurgical device.

Comparison to Predicate Devices:

The Somnus Model 3000 Disposable Tri-Needle Coagulating Electrode has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance validation testing has been done to validate the performance of the device. The comparison and validation results presented in this 510(k) notification to the FDA show that the device is substantially equivalent to predicate devices and is safe and effective in its intended use.